DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 2012

AirStrip Technologies, LP
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLP
1394 25th Street NW
Buffalo, MN 55313

Re: K122133
Trade/Device Name: AirStrip Remote Patient Monitoring (RPM) Remote Data Viewing
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (no alarms)
Regulatory Class: Class II
Product Code: MWI
Dated: August 27, 2012
Received: September 26, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use
510(k) Number (if known): K122133

Device Name: AirStrip Remote Patient Monitoring (RPM) Remote Data Viewing software

Indications for Use:
AirStrip RPM is software capable of displaying physiologic and other patient information. This information is generated by other medical devices and patient information system, and not by AirStrip RPM. AirStrip RPM captures this information from these other systems and displays it for clinicians.

AirStrip RPM is intended to be used by clinicians for the following purposes:
- By using a cellular telephone or other device on which AirStrip RPM is installed, to review physiologic data of a patient when the clinician is not at the hospital
- To view the near real-time waveforms remotely
- To remotely review other standard or critical near real-time patient data from the monitored system
- To provide a request for remote consultation regarding a patient's waveform or other data

The AirStrip RPM software can display the following the physiologic data captured by other medical devices:
- ECG Waveform
- Heart Rate Monitored
- Respiratory Rate
- Oxygen Saturation
- Intracranial Pressure
- Central Venous Pressure
- Pulmonary Capillary Wedge Pressure
- Cardiac Index
- Cardiac Output
- Cerebral Perfusion Pressure
- Urine Output
- Urine/Stool Mix Output
- Systolic Blood Pressure Invasive
- Mean Arterial Pressure Invasive
- Diastolic Blood Pressure Invasive
- Systolic Blood Pressure Cuff
- Mean Arterial Pressure Cuff
- Diastolic Blood Pressure Cuff
- Vasoactive Infusions
- Antiarrhythmics
- Sedation
- Paralytics
- Laboratory Data including
  - Blood Gas
  - Chemistry
  - Hematology
  - Coagulation
- Allergies
- Medications

Counter-Indications
AirStrip RPM software is intended for installation on cellular telephones and other wireless devices, and is not intended for use anywhere cellular telephones or wireless devices are prohibited. AirStrip RPM is intended for use by clinicians when they cannot be at the hospital. AirStrip RPM is intended for use by clinicians as a diagnostic aid, and not as a replacement for direct viewing of any of the monitoring devices from which it obtains its data.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122133